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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,156	07/30/2001	Francis Barany	19603/448 (CRF D-1593C)	4406

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EXAMINER
HORLICK, KENNETH R

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/918,156	BARANY ET AL.	
	Examiner	Art Unit	
	Kenneth R Horlick	1637	

-- The MAILING DATE of this communication app ars n the cover sheet with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 55-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 59-70* is/are rejected.

7)☒ Claim(s) *10 and 55-58* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *18* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 08/06/03 has been entered.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 3, and 4 are rejected under 35 U.S.C. 102(a) as being anticipated by Carrino (WO 96/15271).

These claims are drawn to methods comprising: carrying out a ligation detection reaction using probes containing primer binding sites at the appropriate ends, and then carrying out a polymerase chain reaction on the ligated products using primers targeting said primer binding sites.

Carrino clearly discloses such a method; see pages 11-17 and Figs. 3a-3h.

4. Claims 1, 3, and 4 are rejected under 35 U.S.C. 102(a) as being anticipated by Zhang (WO 95/35390).

This document clearly discloses the claimed method; see pages 5-37 and Fig. 2.

5. Claims 1, 3, and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhang et al. (US 5,876,924). Priority for the combined LDR/PCR method as shown in Fig. 2 of this patent has been confirmed in the parent '937 application, which has a filing date of June 22, 1994.

This document clearly discloses the claimed method; see especially columns 3-18 and Figs. 2 and 13.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 5-9, and 64-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Carrino, WO 95/35390, or Zhang et al. '924.

These claims are drawn to the methods as described and rejected above, with further limitations regarding: use of restriction sites in probes, arrays, quantifying, separation by size differences, particular ligase detection reaction parameters, and particular probe characteristics.

While the further limitations are not explicitly taught in the references, these all unquestionably relate to reaction parameters well known and commonly used in the art at the time of the invention, and as such do not bear on patentability. One of ordinary skill in the art would have been motivated to carry out these minor modifications to the method of any one of the cited references in order to achieve the expected desired results or routine optimization of reaction conditions. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

7. Claims 59-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Carrino, WO 95/35390, or Zhang et al. '924, in view of Gelfand et al. (US 5,418,149).

These claims are drawn to the method of claim 1 as described and rejected above, with further limitations regarding the use of dUTP and uracil N-glycosylase.

The primary references do not disclose the use of dUTP and uracil N-glycosylase for the purpose of rendering amplification products incapable of further amplification.

Gelfand et al. disclose the advantageous use of dUTP and uracil N-glycosylase for the purpose of rendering amplification products incapable of further amplification (see columns 2-28). Both PCR and LDR amplification methodologies are discussed.

One of ordinary skill in the art would have been motivated to use dUTP and uracil N-glycosylase in the method of any one of the primary references because Gelfand et al. taught that this was advantageous in rendering amplification products incapable of further amplification. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

8. Claims 10 and 55-58 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. These claims require the use of blocking groups and exonuclease digestion. While Carrino, Zhang, and Zhang et al. teach an application using exonuclease in the case of a circular probe, there is no

teaching or suggestion of the use of blocking groups in probes and subsequent exonuclease digestion.

9. No claims are allowable.

10. Zhang et al. (US 6,569,647 and US 5,942,391) are made of record as references of interest.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kenneth R. Horlick, Ph.D.
Kenneth R Horlick
Primary Examiner
Art Unit 1637

08/26/03